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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
JB06017US01

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

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Signature _____

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Application Number	Filed
10/822,254	04/09/2004

First Named Inventor
Shahriar Shane Taremi

Art Unit	Examiner
1656	David J. Steadman

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

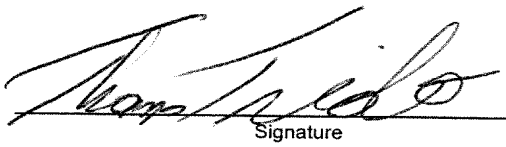
I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 48,001

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____


Signature

Thomas A. Triolo
Typed or printed name

908-298-2347
Telephone number

July 15, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

APPENDIX TO PRE-APPEAL BRIEF REQUEST FOR REVIEW
IN APPLICATION NO. 10/822,254

The present appendix sets forth, briefly, the issues to be appealed and the applicants' arguments with respect to the issues.

Claim rejections under
35 U.S.C. § 112(¶1)-Written Description

Claims 1, 2, 15 and 36-39 stand rejected for an alleged lack of written description. The claims are directed, very generally, to "purified polypeptide[s]" complexed with various other molecules. The Examiner contends that these claims encompass crystalline polypeptides and complexes thereof, and argues that the specification only describes a few representative species of the claimed genus. The examiner took the position that only claims directed to non-crystalline polypeptides would be adequately described. The applicants do not disagree with the examiner's interpretation as to the scope of the claims. *Any* polypeptide comprising the elements specified in the claims are encompassed.

The applicants believe, however, that the examiner is incorrect based on both the case law and various pronouncements of patent examination policy by the USPTO. Indeed, the case law has held, for many years, that disclosure of a polypeptide's amino acid sequence is sufficient description. The applicants are unaware of any court opinion or USPTO guideline or commentary, *ever*, for any reason, requiring a claim directed to a polypeptide to be limited to non-crystalline polypeptides. This amounts to a truly new and, heretofore, unheard-of requirement for patentability which the examiner is arbitrarily imposing on the applicants.

The case law discussed below concerned claims covering polynucleotides and polypeptides wherein the amino acid or nucleotide sequence was adequate description in spite of the fact that the disputed claims encompassed crystals (claim construction is discussed in detail below). Though the courts do not appear to have addressed this issue head-on, the case law points to an understanding of the Written Description requirement which dictates that the amino acid sequence of a claimed polypeptide is sufficient to establish possession of the claimed polypeptide *in all physical forms*.

At the outset, the examiner's apparent belief that the quantity of necessary written support always correlates directly with the scope of the claim is incorrect. The Courts have ruled that claims with additional limitations (*i.e.*, narrower claims) require additional written support for those limitations; whereas, claims without such limitations may be compliant with the written description requirement even in the absence of such support. For example, in *In re Smith*, the CCPA pointed out that a given description may be sufficient to support a broad claim, but not a narrow claim. 59 C.C.P.A. 1025 (C.C.P.A. 1972) [some legal citations will be omitted for brevity/available in the record or upon request]. The applicant, Smith, argued that if a broad genus covering an emulsive coating were described and, thus, entitled to priority under 35 U.S.C. § 120, then a narrower subgenus must also be entitled to priority. The Court disagreed stating "We see nothing inherently wrong with a particular principle of patentability which under certain circumstances operates to defeat the patentability

of a narrow, but not a broader, claim, and, ordinarily, the mere fact that under such a principle a broader claim would pass muster is not a basis for adjusting the principle to render the narrower claim patentable." *Id.* at 1034. Thus, a corollary to this holding is that the present claim 1 (reciting "A purified polypeptide. . ."), written broadly, would require less supporting description than a narrower, analogously worded, claim specifying, for example, "A crystalline purified polypeptide. . ." Specifically, description of every crystal is unnecessary to support a claim to a "purified polypeptide". This principle set forth in *Smith* is in accord with later case law relating to written description.

Fiers, *Lilly* and *Invitrogen* (discussed below) stand for the position that disclosure of a nucleotide or amino acid sequence in a case claiming, generally, "An isolated polypeptide" or "An isolated polynucleotide" is sufficient description. None of the cases recite the additional requirement of, for example, description of crystalline forms of the claimed molecules, or, in the absence of such data, exclusion of such molecules in crystalline form from the claims.

In *Fiers v. Revel*, the Federal Circuit held that the nucleotide sequence of a claimed DNA molecule (not limited to non-crystalline molecules) constitutes adequate written description. In *Fiers*, an issue was whether appellee-Sugano was entitled to his priority date for DNA encoding interferon. The *Fiers* Court held that Sugano was entitled to his filing date since he had satisfied the Written Description requirement with regard to the claimed DNA. Specifically, the Court found that, as of this date, Sugano had provided a complete sequence for the claimed molecule. The *Fiers* Court stated as follows:

> We also conclude that Sugano's application satisfies the written description requirement since it sets forth the complete and correct nucleotide sequence of a DNA coding for B-IF and thus "convey[s] with reasonable clarity to those skilled in the art that, as of the filing date sought, [Sugano] was in possession of the [DNA coding for B-IF]. (emphasis added)

Fiers relates to the description of DNA and not protein; however, its holding can clearly be applied to the instant case. Both DNA and protein are polymeric biomolecules, composed of a limited number of types of subunits, which can exist in crystalline or non-crystalline forms.

Later, *Fiers* was cited in the holding of the case of *Regents of University of California v. Eli Lilly & Co.* In *Lilly*, the Federal Circuit addressed whether claims directed to cDNA encoding insulin, were sufficiently described. The Court found the claims invalid because the cDNA was not sufficiently described. In making this finding, the Court exemplified what is necessary for cDNA to be sufficiently described. The Court, referring to *Fiers*, stated that compliance with the requirement "requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA."

A further relevant case from the Federal Circuit is *Invitrogen Corp. v. Clontech Labs., Inc.* In this case, the Court examined whether a patent directed to a polypeptide with DNA polymerase activity was

compliant with the Written Description requirement. A claim, pointed out by the Court, read as follows:

> 1. An isolated polypeptide having DNA polymerase activity and substantially reduced RNase H activity, wherein said polypeptide is encoded by a modified reverse transcriptase nucleotide sequence that encodes a modified amino acid sequence resulting in said polypeptide having substantially reduced RNase H activity, and wherein said nucleotide sequence is derived from an organism selected from the group consisting of a retrovirus, yeast, Neurospora, Drosophila, primates and rodents.

The specification provided an amino acid sequence and related sequences were known in the art. The Court found the claims to be sufficiently described, in part, because "the shared written description for the patents-in-issue recites both the DNA and amino acid sequences of a representative embodiment of the claimed RT enzyme." Here, the Court found the claimed polypeptides to be sufficiently described on the basis of disclosure of amino acid sequence data.

Furthermore, as mentioned above, the USPTO Written Description Guidelines and the Office's expressions of official policy in reports of the Trilateral Project further substantiate the applicants' point. In these sources, claims worded analogously to the instant claims were found described on the basis of the amino acid sequence. None of the claims were limited to non-crystalline polypeptides.

Example 13 of the Written Description Guidelines considered a hypothetical claim:

> 1. An isolated protein having SEQ ID NO: 3.

; wherein the hypothetical specification disclosed the SEQ ID NO: 3 amino acid sequence. This claim was adequately described in spite of the fact that no description of crystalline molecules was mentioned in the hypothetical specification and the claims did not exclude crystalline proteins.

The Trilateral Project "Report on Comparative Study on Biotechnology Patent Practices Carried Out Under Trilateral Project B3b" provides further support. In example 1 of "Annex 1: Comments of the USPTO", the USPTO discussed an application with the hypothetical claim:

> 1. An isolated and purified receptor the sequence of which consists of SEQ ID NO: 1

SEQ ID NO: 1 was an amino acid sequence. This claim was adequately described. Again, the claims did not exclude crystalline receptors and there was no mention of a description of all crystals in the specification.

In case 5 of the USPTO comments in the Trilateral Project WM4, "Comparative study on protein 3-dimensional (3-D) structure related claims", the hypothetical applicants sought the following two claims:

Claim 1: An isolated and purified molecule comprising a binding pocket of protein P defined by the structural coordinates of amino acid residues 223, 224, 227, 295, 343, 366, 370, 378 and 384 according to Figure 1.

Claim 2: An isolated and purified polypeptide consisting of a portion of protein P starting at one of amino acids 214 to 218 and ending at one of amino acids 394 to 401 of protein P as set forth in SEQ ID NO: 1.

Here, the specification specifically discussed a crystal of the claimed protein. Nevertheless, the claims, as written, were found to be adequately described in spite of the fact that they do not exclude crystalline polypeptides. There was no mention of any need to describe an extensive number of crystals of the claimed polypeptide.

The arbitrary nature of the examiner's requirements are obvious when one considers the fact that polypeptides may exist in a multitude of states, for which the examiner has not required any support. For example, polypeptides can exist as amorphous precipitates, microcrystals, disordered crystals and semi-solids; yet, the examiner has selected diffraction quality crystals as the embodiment for which an extensive amount of supporting disclosure is required. This is arbitrary and utterly unsupported by the case law. None of these embodiments require this extensive quantity of description for the types of claims at issue.

Claim rejections under 35 U.S.C. § 112(¶1)-Enablement

The examiner took the position that the specification has not taught how to make and use the crystals encompassed by the scope of the claims. The examiner is mistaken in view of several sources including those discussed below.

The scope of enablement must "*only* bear a "reasonable correlation" to the scope of the claims." M.P.E.P. § 2164.08 (emphasis added). Thus, it is not necessary to show, exhaustively, how to make every last embodiment covered by the claims. This has *never* been a requirement for patentability and is being arbitrarily imposed on the Applicants. Again, the examiner has selected diffraction quality crystals as requiring extensive supporting discussions.

Considering the full scope of the claimed subject matter, the disclosure *does* reasonably correlate with the claim scope. The specification discloses two crystals and how to make the crystals (see examples 2-3). Moreover, the examiner has not alleged that soluble polypeptides (including complexes and fusions) and polypeptides in other physical states, which comprise a large portion of the subject matter encompassed by the claims, are enabled. Even if generation of further crystals needed to be exemplified, screening for the additional crystals, using the specification as a guide, would not require undue amounts of experimentation. Screening for crystallization conditions has become a high-throughput endeavor wherein thousands of conditions can be screened quickly by automated procedures. There are several commercial products and companies which are based upon this fact.

The Comments of the USPTO on Trilateral Project WM4, "Comparative study on protein 3-dimensional (3-D) structure related claims" provide

support for this position. The Comments considered the enablement of the hypothetical claim:

> An isolated and purified molecule comprising a binding pocket of protein P defined by the structural coordinates of amino acid residues 223, 224, 227, 295, 343, 366, 370, 378 and 384 according to Figure 1.

The specification specifically discussed X-ray diffraction data of the claimed protein. There was no mention whatsoever, in the discussion of enablement, about limiting the claims to non-crystalline proteins. Claim 2 was deemed enabled. The discussion stated that "[w]ith respect to the enablement requirement, the specification enables the full-length protein P and the specifically disclosed fragments."

Finally, the "Training Materials for Examining Patent Applications with Respect to 35 USC Section 112, First Paragraph-Enablement of Chemical/Biotechnical Applications", discusses a hypothetical claim at Example 5E (abbreviated):

> 1. A peptide consisting of the sequence. . .

; wherein the specification teaches how to make such polypeptides. Respecting the "how to make" prong of enablement, the claim was found sufficiently enabled according to the materials.

A counter-argument offered by the examiner is that the claims at issue in the cases cited and in the Guideline and Comments presented did not included crystals. We disagree and Federal Circuit case law disagrees with this mode of claim interpretation. For example, in *Liebel-Flarsheim Co. v. Medrad, Inc*, the Federal Circuit stated that "absent a clear disclaimer of particular subject matter, the fact that the inventor may have anticipated that the invention would be used in a particular way does not mean that the scope of the invention is limited to that context." Thus, the claims are generally not limited to what is discussed in the specification in the absence of a disclaimer. There is no evidence such a disclaimer was made in any of the cases discussed and, indeed, it is highly unlikely. See also, *Phillips v. AWH Corp*. Thus, the claims discussed above would have been interpreted as encompassing *any* polypeptide exhibiting the elements specified-crystalline or non-crystalline. For example, it is irrelevant that the Written Description Guidelines do not mention crystals. A court would interpret the hypothetical claims to cover polypeptides in any physical state, crystalline, soluble or otherwise.

The examiner also argued that that the Guidelines and Comments cited in the arguments in support of patentability were not persuasive since such sources do not create a rigid test, but, rather, are only helpful in applying relevant law. The examiner, however, seems to summarily reject the Guidelines and Comments for no apparent reason. The examiner, without explanation, dismissed any persuasive value of the Guidelines and argued that the claims were not enabled (see *e.g.*, page 12 of Apr. 15, 2008 office action). In the absence of any specific reason for disregarding such Guidelines and Comments, ignoring them appears arbitrary and improper. The examiner has not articulated such a reason.